4 LIDOCAINE TOPICAL ANESTHETIC- lidocaine cream RUGBY LABORATORIES

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

4% Lidocaine Topical Anesthetic Cream

Drug Facts

Active ingredient

Active ingredient

Purpose

Topical Analgesic

Uses

temporarily relieves pain and itching due to:

- minor cuts
- minor scrapes
- sunburn
- minor skin irritations
- minor burns
- insect bites

Warnings

For external use only.

When using this product

- do not use in or near the eyes
- do not use in large quantities, particularly over raw surfaces or blistered areas.

Stop use and ask a doctor if

- Allergic reaction occurs
- condition worsens or does not improve within 7 days
- symptoms clear up and return within a few days
- redness, irritation, swelling, pain or other symptoms begin or increase

Do not apply over large areas of the body.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- Adults and children 2 years and older: Apply externally to the affected area up to 3-4 times daily.
- Children under 2 years: Consult a doctor.

Other information

• Store at USP controlled room temperature 20° to 25°C (68° to 77°F)

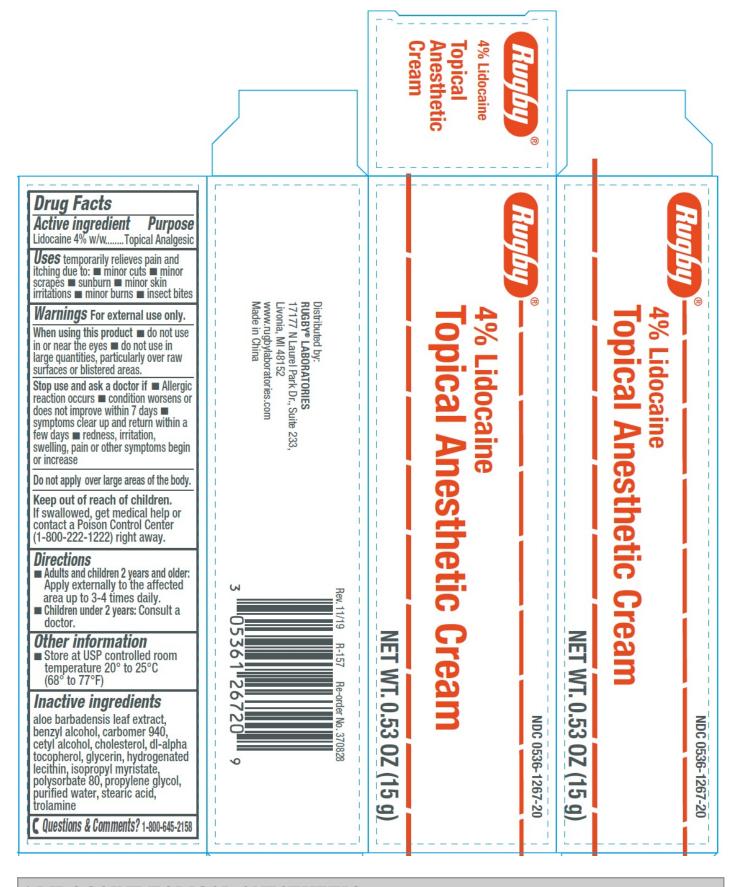
Inactive ingredients

aloe barbadensis leaf extract, benzyl alcohol, carbomer 940, cetyl alcohol, cholesterol, di-alpha tocopherol, glycerin, hydrogenated lecithin, isopropyl myristate, polysorbate 80, propylene glycol, purified water, stearic acid, trolamine

Questions & Comments?

1-800-645-2158

Package Labeling:



4 LIDOCAINE TOPICAL ANESTHETIC

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1267
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LIDO CAINE (UNII: 98 PI200 987) (LIDO CAINE - UNII: 98 PI200 987)	LIDOCAINE	40 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
CHOLESTEROL (UNII: 97C5T2UQ7J)		
.ALPHATO COPHEROL, DL- (UNII: 7QWA1RIO01)		
GLYCERIN (UNII: PDC6A3C0OX)		
HYDRO GENATED SO YBEAN LECITHIN (UNII: H1109Z9J4N)		
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TROLAMINE (UNII: 903K93S3TK)		

Pa	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1267-20	15 g in 1 BOX; Type 0: Not a Combination Product	04/30/2020	

Marketing Inform	arketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	04/30/2020		

Labeler - RUGBY LABORATORIES (079246066)

Revised: 4/2020 RUGBY LABORATORIES